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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,864 / 23464 7590	10/13/2000 06/16/2003	Jeffrey A. Ledbetter	034474.0003 UTLI	1294

BUCHANAN INGERSOLL, P.C.  
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PITTSBURGH, PA 15219

EXAMINER
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PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/687,864

Applicant(s)

LEDBETTER ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Applicants: Ledbetter, J. A., and  
M. Hayden-Ledbetter

Docket No.: 034474.0003  
Filing Date: 10/13/00

### Restriction Requirement

#### 35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- 5 a. Group I, claim(s) 1-14, drawn to vaccines comprising a **fusion protein** containing an **antigenic domain** linked to a **receptor binding domain** and expression vectors encoding said proteins, classified in class 435, subclass 69.7, class 424, subclasses 192.1, 208.1, 234.1, and 277.1, and class 530, subclass 350.

10 2. Applicants are advised that each combination of an antigenic domain (e.g., HIV-1 gp160, tumor antigen, bacterial antigen) and receptor binding domain (e.g., CD40-binding, CD154, single chain Fv, CD80-binding, CD86-binding, etc.) constitutes an independent and distinct invention.<sup>1</sup> Accordingly, **a single antigenic domain and a single receptor binding domain should be elected pursuant to**

15 **35 U.S.C. § 121.** This is **NOT** a species election requirement. Each of the identified fusion proteins are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and §

20 808.01). In the instant case, each fusion protein will have a substantially different structure and attendant biochemical and immunological properties. Moreover, separate searches will be required for each invention.

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<sup>1</sup> Due to the inordinate number of inventions (e.g., HIV-1 gp160-CD154, HIV-1 gp160-single chain Fv, HIV-1 gp160-CD80-binding domain, HIV-1 gp160-CD86 binding domain, bacterial antigen-CD154, bacterial antigen-single chain Fv, bacterial antigen-CD80-binding domain, bacterial antigen-CD86 binding domain, tumor antigen-CD154, tumor antigen-single chain Fv, tumor antigen-CD80-binding domain, tumor antigen-CD86 binding domain, etc.) it was not feasible to set forth each one individually. However, as set forth in the restriction requirement, each combination of antigen and receptor binding domain constitutes an independent and distinct invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

#### *Correspondence*

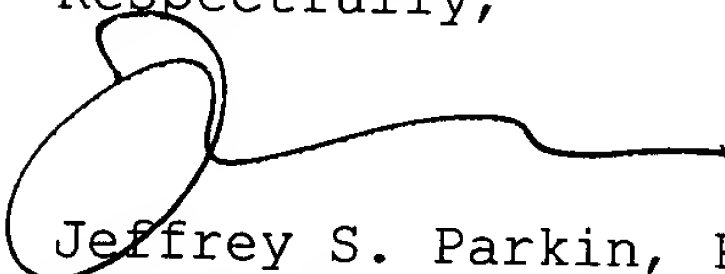
6. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

7. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie

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Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

13 June, 2003